UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF INDIANA
HAMMOND DIVISION

CHERYL J. CUNNINGHAM, Individually and as Personal Representative of the Estate of SCOTT RANDALL CUNNINGHAM, Deceased, JOHN J. CUNNINGHAM, Individually; and KEVIN CUNNINGHAM, Individually,	)	
Plaintiffs	)	
v.	)	Case No. 2:07 cv 174
SMITHKLINE BEECHAM d/b/a GLAXOSMITHKLINE,	)	
Defendant	)	

OPINION AND ORDER

This matter is before the court on the Motion to Conditionally Seal Documents filed by the plaintiffs on February 29, 2008 (DE 58); the Motion to File Under Seal Certain Exhibits to Dr. Barbara Arning's Declaration filed by the defendant, Smithkline Beecham, on March 25, 2008 (DE 88); the Motion to File Under Seal "Appendix A" and Certain Exhibits filed by the defendant, Smithkline Beecham, on March 25, 2008 (DE 85); and the Motion for Leave to File Under Seal Plaintiffs' Exhibits C and M filed by the plaintiffs on May 7, 2008 (DE 104).

For the reasons set forth below, the Motion to Conditionally Seal Documents filed by the plaintiffs on February 29, 2008 (DE 58) is **GRANTED**; the Motion to File Under Seal Certain Exhibits filed by the defendant, Smithkline Beecham, on March 25, 2008 (DE

88) and the Motion to File Under Seal "Appendix A" filed by the defendant, Smithkline Beecham, on March 25, 2008 (DE 85) are **DENIED;** and the Motion for Leave to File Under Seal Plaintiffs' Exhibits C and M filed by the plaintiffs on May 7, 2008 (DE 104) is **DENIED.**

Background

This case arises from the suicide of 14-year old Scott Cunningham in March 2001. In their complaint, the plaintiffs, Scott Cunningham's mother, father, and brother, allege that his suicide was caused by the prescription anti-depressant marketed under the name Paxil and manufactured by the defendant Smithkline Beecham.

The plaintiffs allege that beginning in 1994, Glaxosmith-kline (Smithkline) became aware that Paxil was ineffective for the treatment of depression in adolescents and that the drug increased the risk of suicide in adolescent patients. The plaintiffs further contend that Smithkline knew that, despite the lack of approval for use in treating adolescent depression, so-called "off-label" prescriptions of Paxil were sufficient to make the drug the second most prescribed anti-depressant for children and adolescents. The plaintiffs allege that through a series of conferences, articles, and other promotional efforts, including the use of paid "opinion leaders," Smithkline promoted the use of Paxil for children.

On September 28, 2007, this court entered an agreed Protective Order which permitted the parties to file under seal confi-

dential information. The parties defined confidential information as "confidential research, development, trade secrets, commercial information, competitively-sensitive information, as well as patient-or-reporter-identifying information protected from disclosure by state or federal law." (See Protective Order, September 28, 2007, pp. 1-2) The order permitted the parties to designate documents that met this criteria as "confidential."

On January 25, 2008, the defendant moved for summary judgment. The plaintiffs filed their response together with the pending motions seeking to unseal documents that Smithkline had provided marked as "confidential." In addition, Smithkline, in response to the plaintiffs' statement of genuine issues filed in response to its motion for summary judgment, filed a motion to strike and, in conjunction with that motion, a motion to file additional documents under seal.

Discussion

Federal Rule of Civil Procedure 26(c) provides that good cause must support the sealing of a portion of a pre-trial record. ***Citizens First National Bank of Princeton v. Cincinnati Insurance Company***, 178 F.3d 943, 946 (7th Cir. 1999)("Most cases endorse a presumption of public access to discovery materials, and therefor require a district court to make a determination of good cause before he may enter the order."). In order to find sufficient cause to shield presumptively public documents, "a litigant must do more than just identify a kind of information and demand secrecy." ***Composite Marine Propellers, Inc. v. Van Der***

Woude, 962 F.2d 1263, 1266 (7th Cir. 1992). *See also* ***In re Bank One Securities Litigation***, 222 F.R.D. 582, 588 (N.D. Ill. 2004) (*quoting* ***Gulf Oil v. Bernard***, 452 U.S. 89, 102, 101 S.Ct. 2193, 2201, 68 L.Ed.2d 693 (1981)("[I]t is not enough that a party seeking the protection of an alleged trade secret simply states that a document contains a trade secret, as good cause does not permit 'stereotyped and conclusory statements.'").

Instead, a litigant's effort to seal a portion of the record must reach beyond "a bald assertion that confidentiality promotes their business interest." ***Baxter International, Inc. v. Abbot Laboratories***, 297 F.3d 544, 547 (7th Cir. 2002). A party's entitlement to protection must find its roots in the law of trade secrets, privilege, or statutory entitlement. ***Baxter International***, 297 F.3d at 547.

In this matter, the parties' dispute focuses upon whether certain information is confidential in light of Food and Drug Administration regulations and Smithkline's assertion that the information contains trade secrets. Regarding the application of trade secret law, the court first notes that the parties, whose summary judgment dispute largely revolves around the application of the choice of law doctrine, appear to agree that the substantive question of defining a trade secret is a matter of Indiana law. The court is not required to look beyond the parties' agreement upon this point. ***Peterson v. Sealed Air Corp.***, 902 F.2d 1232, 1234 (7th Cir. 1990); ***United States Gypsum Company v.***

LaFarge North America, Inc., 508 F.Supp.2d 601, 623 (N.D. Ill. 2007).

Under Indiana's adoption of the Uniform Trade Secrets Act

> "Trade secret" means information, including a formula, pattern, compilation, program, device, method, technique, or process, that: (1) derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use; and (2) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.
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> IC § 24-2-3-2

See also ***Paramanandam v. Herrmann***, 827 N.E.2d 1173, 1180 (Ind. App. 2005).

Over the course of briefing, the parties agree that some of the initial set of documents are not entitled to protection. Specifically, the parties agree that sealing Exhibits 10, 13, 16, 17, 41, and 50 to the Declaration of George Murgatroyd III and Exhibit 1 to the Declaration of Joseph Glenmullen MD is not justified. In addition, on June 9, 2008, Smithkline indicated that it did not claim confidentiality with respect to Exhibits 3, 4, and 16 to the Declaration of Dr. Barbara Arning, filed in support of its motion to strike the plaintiffs' statement of genuine issues.

With respect to the remaining documents, Smithkline makes the general statement that each document "contain[s] sensitive information which GSK has conscientiously protected from disclosure." (Response in Opposition, p. 10) In support of the state-

ment, Smithkline has cited to the declaration of its document custodian, Barbara Weber, who has indicated that the New Drug Application (NDA) for Paxil "contains trade secrets" that are "maintained in the strictest confidence." Weber contends that Murgatroyd Exhibits 3, 8, 9, and 12 contain documents submitted with the NDA, Exhibits 7 and 11 include deposition testimony discussing this information, and that others, specifically Murgatroyd Exhibits 15, 29, and 57, contain confidential discussions of Smithkline's "Global Safety Board" and marketing personnel. Weber also has stated that the additional exhibits - Exhibit 2 to the Glenmullen Declaration and Exhibit 1 to the Grimson Declaration - "contain sensitive and confidential commercial information, research, development information and trade secrets."

Smithkline's argument provides little more than the conclusion that the information contains a trade secret without reference to any basis for the conclusion. More is demanded in the Seventh Circuit:

> Beyond asserting that the document must be kept confidential because we say so (the "agreement is, by its terms, confidential"), this contends only that disclosure "could . . . harm Abbott's competitive position." How? Not explained. Why is this sort of harm (whatever it may be) a legal justification for secrecy in litigation? Not explained. Why is the fact that some other document contains references to a license sufficient to conceal the referring document? Not explained.
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> ***Baxter International, Inc.***, 297 F.3d at 547

Beyond its general assertions, Smithkline further has indicated that much of this information was included in the New Drug Application (NDA) for Paxil and correspondence conducted with the FDA and, consequently, is subject to protection pursuant to the regulations governing the new drug approval process.

In the process of obtaining FDA approval of a new drug, before undertaking testing on human subjects, the drug's sponsor must submit an investigational new drug application (IND). After 30 days, a sponsor may conduct clinical (i.e. human) testing and, during the course of this period, must update the IND application with any changes in testing protocol (21 C.F.R. §312.20), new information regarding "toxicology, chemistry or other technical information" (21 C.F.R. §312.31), safety reports indicating adverse reactions (21 C.F.R. §312.32), and within 60 days of the IND application, a "brief" progress report of the testing. (21 C.F.R. §312.33).

The standards governing the new drug application, the next stage of the process, require that the NDA include

> (A) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use; (B) a full list of the articles used as components of such drug; (C) a full statement of the composition of such drug; (D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (E) such samples of such drug and of the articles used as components thereof as the Secretary may require; (F) specimens of the labeling proposed to be used for such drug.

21 U.S.C.A. §355(b)(1)

In addition, a series of regulations with roots in the Freedom of Information Act addresses the public availability of information submitted in a new drug application. These regulations provide that once an NDA no longer is pending, absent "extraordinary circumstances," summaries of safety and effectiveness data, test protocol, and adverse reaction reports are available publically, with some limits. *See* 21 C.F.R. §§314.430 (e), (g) and (f). One of those limits provides that trade secrets also are exempt from disclosure by the FDA pursuant to 21 C.F.R. §20.61. This provision governs the acts of the FDA, prohibiting the agency from publicly releasing trade secrets or confidential commercial information that have been submitted during the course of drug approval. The FDA is not a party in this matter, which regards a dispute between private entities. However, because the regulations bear upon the public release of this information, the regulatory framework is analogous and conceivably the source of a statutory entitlement to protection.

Section 20.61 separately addresses a category of trade secrets and a category of "confidential commercial or financial" information. First, according to the regulation, a trade secret is

> any commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. There must be a direct rela-

> tionship between the trade secret and the productive process.
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> 21 C.F.R. §20.61(a)

In ***Public Citizen Health Research Group v. Food and Drug Administration***, 704 F.2d 1280, 1289 (D.C. Cir. 1983), the court adopted a narrow definition of trade secret relative to the Restatement of Torts definition, noting that "[i]f a trade secret can be any information used in a business which gives a competitive advantage, then there is little or no information left that could qualify as commercial or financial information under the second category of the exemption without also qualifying as a trade secret."

This second category in the regulation defines confidential commercial or financial information as "information which is used in one's business and is of a type customarily held in strict confidence or regarded as privileged and not disclosed to any member of the public by the person to whom it belongs." 21 C.F.R. §20.61(b). This standard, like that described by the Seventh Circuit, cannot be met with "conclusory and generalized allegation of substantial competitive harm." ***Public Citizen,*** 704 F.2d at 1291.

As already noted, Smithkline has offered little more than such generalized allegations. For example, Smithkline states that "This confidential information must be held from GSK's competitors to prevent them from obtaining a competitive advantage in the relevant markets." From among the numerous documents at

issue, Smithkline does not point to any particular detail in support of this statement, explain the nature of a competitive injury, or further specify some "relevant market." Smithkline also notes that unsealing the documents would permit public access to "sensitive and confidential communications between GSK and FDA concerning the reporting on and submission of data collected from clinical trials of Paxil." This, however, appears to be precisely the information that the FDA regulations make public once a drug's NDA no longer is pending. In making the argument, Smithkline fails to recognize the existence of a distinction between the two prongs of the FDA regulation governing both trade secrets and, separately defined, confidential commercial information. Smithkline summarily has stated that analysis of suicide data falls within the exemption for both. This statement is not accompanied by any explanation describing how the release of this information may cause a competitive injury. *See e.g.* ***Public Citizen***, 704 F.2d at 1291 n.30 ("Competitive harm should not be taken to mean simply any injury to competitive position, as might flow from customer or employee disgruntlement or from the embarrassing publicity attendant upon public revelations concerning, for example, illegal or unethical payments to government officials or violations of civil rights, environmental or safety laws.").

The plaintiffs also claim that because Paxil's patent has expired and is subject to generic competition, which could be approved pursuant to the FDA's Abbreviated New Drug Application

process, the FDA's protections no longer are in place. In light of Smithkline's inability to provide any particularity regarding the documents it believes must be kept under seal, the court does not reach this claim. *See e.g.* ***Smithkline Beecham Corp. v. Apotex Corp.***, 383 F.Supp.2d 686, 690 (E.D. Pa. 2004).

Further, a review of the documents which include summaries of efficacy and safety data, summaries of clinical trials, deposition testimony, and internal memorandum, does not support the conclusion that the documents contain trade secrets or if released, that the release itself would cause competitive harm. There is no basis to seal documents that largely are comprised of statistical analyses of the rates of certain reactions to Paxil during the clinical trials, deposition testimony that appears to come nowhere near confidential information, meeting agendas, and in one instance, a copy of an article published in the July 2001 Journal of the American Academy of Child and Adolescent Psychiatry. In its reply brief on the motion to file under seal the appendix to its motion to strike, Smithkline cites to cases for the proposition that documents "containing information consisting of drug product manufacturing information" constitute trade secrets. *See e.g.* ***Andrx Pharmaceuticals, LLC v. Glaxosmithkline, plc.,*** 236 F.R.D. 583, 586 (S.D. Fla. 2006). However, Smithkline has pointed to no document in dispute that contains drug manufacturing or chemical composition information. Further, even if such information was included in the drug's NDA, which presumably no longer is subject to regulatory protection, there is no indica-

tion that these portions of the NDA have been submitted with the record in this case.

Finally, Smithkline has argued that the public interest in disclosure is outweighed by its interest in protecting this material. This nature of balancing, however, is engaged when the court considers the disclosure of information shown to be a trade secret. *See* ***Andrew Corp. v. Rossi***, 180 F.R.D. 338, 340 (N.D. Ill. 1998) ("To obtain a . . . protective order, the movant must show that the interest for which protection is sought is an actual trade secret or other confidential business information protected under the Rule, and that there is good cause for the protective order. When these showings are made, the burden shifts to the respondent to demonstrate that the need for discovery outweighs the need for privacy.")(internal citation and quotations omitted). Because Smithkline has not shown that trade secrets or confidential commercial information are involved, the court does not reach this balancing. Instead, the documents at issues are presumptively public and Smithkline has not shown that this presumption is inapplicable.

Finally, the plaintiffs' motion for leave to file under seal exhibits "C" and "M" to their Motion to Compel regards documents that also were made part of the record with respect to the motion for summary judgment and included in the foregoing discussion. The court has concluded there was no basis to file the documents under seal.

For the foregoing reasons, the Motion to Conditionally Seal Documents filed by the plaintiffs on February 29, 2008 (DE 58) is **GRANTED**; the Motion to File Under Seal Certain Exhibits filed by the defendant, Smithkline Beecham, on March 25, 2008 (DE 88) and the Motion to File Under Seal "Appendix A" filed by the defendant, Smithkline Beecham, on March 25, 2008 (DE 85) are **DENIED**; and the Motion for Leave to File Under Seal Plaintiffs' Exhibits C and M filed by the plaintiffs on May 7, 2008 (DE 104) is **DENIED**. The parties are **DIRECTED** to file the following documents on the court's electronic filing system:

Plaintiffs' Opposition to Defendant Smithkline Beecham Corporation D/B/A Glaxosmithkline's Motion for Summary Judgment;

Plaintiffs' Statement of Genuine Issues Filed In Support of Plaintiffs' Opposition to GSK's Motion for Summary Judgment;

Exhibits 3, 7-13, 15-17, 29, 41, 50 and 57 to the Declaration of George W. Murgatroyd III in Support of Plaintiffs' Opposition to Smithkline Beecham Corporation D/B/A Glaxosmithkline's Motion for Summary Judgment;

Exhibits 1 and 2 to the Declaration of Jospeh Glenmullen, M.D., in Support of Plaintiffs' Opposition to Smithkline Beecham Corporation D/B/A Glaxosmithkline's Motion for Summary Judgment;

Exhibits 1, 3, 4, 16 and 17 to Dr. Barbara Arning's Declaration in Support of Defendant Smithkline Beecham Corporation D/B/A Glaxosmithkline's Motion to Strike Plaintiffs' "Statement of Genuine Issues," and Leave to File a Response to Plaintiffs' "Statement of Genuine Issues";

Exhibits A-C, F and I to Bijan Esfandiari's Declaration in Support of Plaintiffs' Opposition to Defendant Smithkline Beecham Corporation D/B/A Glaxosmithkline's Motion to Strike Plaintiffs' "Statement of Genuine Issues," and Leave to File a Response to Plaintiffs' "Statement of Genuine Issues";

Appendix A and Exhibits 7, 9, 11, 19, 12, 14, 8 and 10 thereto to Defendant Smithkline Beecham Corporation D/B/A Glaxosmithkline's Motion to Strike Plaintiffs' "Statement of Genuine Issues," and Leave to File a Response to Plaintiffs' "Statement of Genuine Issues";

Exhibits "C" and "M" in Support of the Plaintiffs' Motion to Compel Defendant to Provide Substantive Responses and Documents to Plaintiffs' Third Request for Production of Documents, and Request for Sanctions.

ENTERED this 25th day of June, 2008

s/ ANDREW P. RODOVICH
United States Magistrate Judge